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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,250	06/27/2003	Bret A. Ferree	SP110.1	8552

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EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,250

Applicant(s)

FERREE, BRET A.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/2003; 2/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of claims 14-20 in the reply filed on 2/14/2005 is acknowledged. The traversal is on the ground(s) that the claims are directed to similar devices in which the channels are within the body of the device and/or are in the outer surface thereof and it would not be a serious burden to examiner the claims. This is not found persuasive because the species are distinct and the search is extensive ranging from 623/16.11-23.63 some 100+ subclasses in class 623, alone.

Claims 1-13, 16, 17 are withdrawn from further consideration pursuant to 37.CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/14/2005. Examiner, notes that claims 16 and 17 are directed to embodiments not illustrated in elected figure 21, the first figure of the elected device illustrated in the group including 21, 22A and 22B. The illustrated device of figures 22A and 22B differ from the device illustrated in figure 21, in that device depicted in figures 22A and 22B is directed to a femoral prosthesis while the device of figure 21 is directed to an acetabular prosthesis. Accordingly, claims 16 and 17 do not read on the elected figure 21 and are withdrawn from consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19, there is no antecedent support for "said bone growth promoting substance". Claim 19 depends from claim 14 and claim 14 fails to positively claim the bone growth promoting substance in the body of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

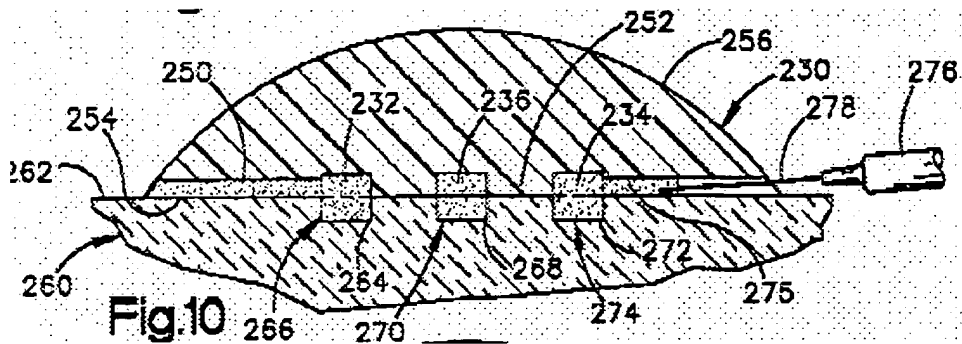
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14,18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (6217617) in view of Urist (4526909).

Bonutti discloses a prosthetic device comprising a body having a first surface for contacting bone and a second surface; and at least one groove (246) located within said first surface each of which opens (240) to said second surface, such that when said device is implanted into bone, a bone growth promoting substance can be inserted into said at least one groove at said second surface such that said substance can travel

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within said. at least one groove on said first surface of said body to promote bone ingrowth between said prosthetic device and the bone. See figure 10.



While Bonutti does not include growth promoting substance in combination with the bone cement, Urist teaches mixing BMP with PMMA to induce formation of new bone.

The delivery composition comprises substantially pure bone morphogenetic protein and polymethylmethacrylate and it is prepared by admixing the bone morphogenetic protein and polymethylmethacrylate. The composition is implanted in viable tissue where the bone morphogenetic protein is slowly released and induces formation of new bone.

To add BMP to the cement of Bonutti or to use the cement composition of Urist to fix the prosthesis to the bone such that the composition will induce new bone formation which serves to reduce the chance of prosthesis failure would have been obvious to one with ordinary skill in the art from the teachings of Urist.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (6217617) as applied to claim 14 above, and further in view of Shaw (3918100). Shaw teaches coating a prosthetic device with a film of bone growth promoting substance for stimulating living bone attachment to the surface of the prosthesis. To coat the bone interface of the prosthesis of Bonutti with a bone growth

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promoting substance to enhance fixation of the prosthesis to the bone would have been obvious from the teachings of Shaw.

A system of coating prostheses with ground bone particles is presented. Prostheses made of various metals and other substances are coated using rf sputtering techniques to form a film which adheres to the device, stimulates living bone attachment thereto and which is ultimately replaced by new bone. Beef cattle bone ma-

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

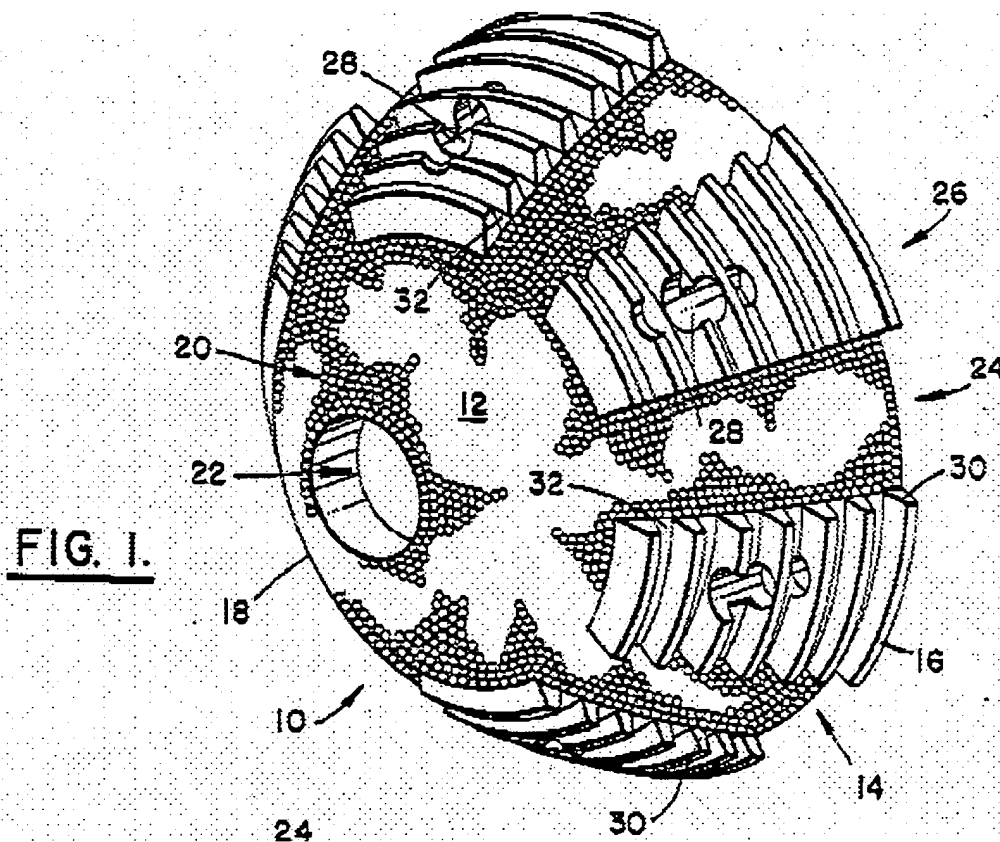
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14,15,18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mallory, et al (4883491).

Mallory et al discloses an acetabular prosthesis (10) comprising a body having a first surface (16) for contacting bone and a second surface (equatorial surface); and at least one groove (14) located within said first surface each of which opens to said second surface, such that when said device is implanted into bone, a bone growth promoting substance can be inserted into said at least one groove at said second surface such that said substance can travel within said at least one groove on said first surface of said body to promote bone ingrowth between said prosthetic device and the

bone. The structure as broadly claimed does not distinguish over the same structure as illustrated in figure 1.



Note, the language "that when said device is implanted into bone, a bone growth promoting substance can be inserted into said at least one groove at said second surface such that said substance can travel within said at least one groove on said first surface of said body to promote bone ingrowth between said prosthetic device and the bone" is functional language and the device as illustrated in figure one is "capable" of performing the steps of inserting a growth promoting substance into the at least one groove at the second surface such that the substance can travel within the groove.

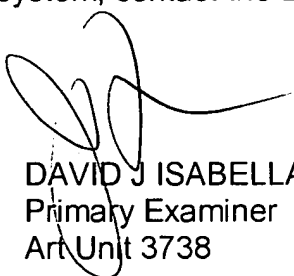
Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mallory et al (4883491) as applied to claim 14 above, and further in view of Shaw (3918100). Shaw teaches coating a prosthetic device with a film of bone growth promoting substance for stimulating living bone attachment to the surface of the prosthesis. To coat the bone interface of the prosthesis of Mallory et al with a bone growth promoting substance to enhance fixation of the prosthesis to the bone would have been obvious from the teachings of Shaw.

A system of coating prostheses with ground bone particles is presented. Prostheses made of various metals and other substances are coated using sputtering techniques to form a film which adheres to the device, stimulates living bone attachment thereto and which is ultimately replaced by new bone. Beef cattle bone ma-

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
4/20/2005